

# EXHIBIT 1

the return of clinical symptoms. I have independently evaluated a number of these adverse event reports and determined that a significant number present cases of olmesartan causality. It is important to recognize that it is an “accepted fact” that adverse events are underreported, as acknowledged by Dr. Allen Feldman of Daiichi Sankyo. (Allen Feldman, 144-145).

Before addressing several MedWatch forms as examples of the numerous reports I have reviewed, I address the methodology of my approach. As with the general approach to assessing the cause of symptoms as discussed above, I formed a differential diagnosis, applied my medical judgment, and used the information available to rule out and rule in potential causes reasonably included in the differential diagnosis. This is the approach utilized by the physicians performing the causality assessments, where performed. In the context of clinical study adverse events, Tina Ho testified: “the medical review specifically is for someone with the medical credential to look at the information and confirm especially the causality.” This is referred to as a “clinical evaluation of the case.” The company protocol required the medical reviewer, “to ensure accuracy and completeness from the clinical perspective.” (Tina Ho, 569-575). With regard to the assessment and reporting of adverse events from non-study sources, Tina Ho testified regarding the company’s protocols, RM-SOI-003, including the criteria and methodology for medical doctors to perform the causality assessments on serious adverse events. Tina Ho confirmed: “you want doctors exercising medical judgment, evaluating the relevant information that’s available to your company to form this judgment, this opinion..” From 2007 to 2009 the definitions utilized were adopted from the WHO-UMC Causality Categories – including definitely related, probably related, possibly related, unlikely related, and unknown (where there is not adequate information to form a valid medical judgment). Tina Ho agreed that in each case,

based on the available information, “you have a medical doctor looking at all of the available information and the person to be able to say, assess that it’s probably related, when they’re looking at the known characteristics of the subject’s clinical state, that’s differential diagnosis; that’s looking at what disease does the person have, what’s their comorbidities, what other drugs were they taking, I mean, looking at their whole picture..” Finally, and most important, **“In the individual case that’s being evaluated, if either probably related or definitely related is checked, that means the medical reviewer felt that in that patient’s case, the side effect being looked at was likely caused by the drug for that patient.”** (Tina Ho, 606:24-617:14). In April, 2009 the SOI was modified to limit the available labels to related or unrelated, however Tina Ho confirmed the same process would be followed as with the former criteria, and a finding of related would equate to the top half of the list and a finding of unrelated would equate to the bottom half of the list. (Tina Ho, 619-620). The criteria for the protocols governing evaluation of adverse events from clinical studies were essentially the same, and were also changed in April, 2009 to simplify to related and unrelated. In discussing a powerpoint illustrating that change in terminology, Tina Ho confirmed, “there’s actually definitions of the related and not related, which, again, just lumps in the different clinical criteria that the medical reviewer would be applying and doing a differential and exercising medical judgment.” (Tina Ho, 632-633). Finally, Tina Ho confirmed that the related/unrelated terminology is not something created by Daiichi Sankyo, it is “a validated industry standard methodology.” (Tina Ho, 627-628).

Tina Ho was presented with a MedWatch report for an adverse event reported to Daiichi Sankyo by a physician on October 19, 2006. The reported clinical information included diarrhea and vomiting, weight loss, hospitalizations, and a positive dechallenge, then a positive



rechallenge. The causality was assessed as “definite.” Tina Ho confirmed, “the medical doctor who evaluated this agreed that, you know, when we have a rechallenge here, in light of all the other information, there’s a definite relationship.” (Tina Ho, 621:7-623:12). My independent evaluation of this report is consistent with that of the reporter and the medical reviewer at Daiichi Sankyo.

Medwatch report number SU-2007-005968, bates number OLM-DSI-0004774183, deposition exhibit 347, reported to Daiichi Sankyo on March 22, 2007, discusses a patient with reported massive diarrhea, severe dehydration, and a 20 pound weight loss. There is positive dechallenge and positive rechallenge, as the symptoms abated when the medication was stopped, and the symptoms recurred when the medication was restarted. This clinical picture fits well with the clinical picture of patients discussed in Rubio-Tapia, and the numerous pertinent studies and case reports in the literature. Although there is no biopsy referenced, and no celiac disease testing referenced, a clinical diagnosis can be formed to a reasonable degree of medical certainty that the most likely cause of the clinical presentation discussed is the olmesartan. This is because the clinical symptoms are consistent, and the documented dechallenge and rechallenge is essentially decisive clinical information since it is medically improbable that there could be a different cause such as celiac disease, IBD, or autoimmune enteropathy, with the symptoms abating and/or recurring in correlation to whether or not the patient was using olmesartan. It should also be noted that the rate of duodenal biopsy is low in comparison to the number of patients with clinical indications for biopsy during upper endoscopy, so there may be a large number of patients with olmesartan enteropathy but no biopsy. Lebwohl, et al. **Sex and racial disparities in duodenal biopsy to evaluate for celiac disease.** Gastrointest Endosc

2012;76:779-85. If this patient were presented to our practice, in person or for phone consultation, as often happens, the leading diagnosis would be olmesartan enteropathy. Allen Feldman, a medical doctor and the Vice President of Pharmacovigilance at Daiichi Sankyo testified in his deposition that the only plausible cause of this patient's illness was olmesartan (Feldman, 273-274, 283-285), which is further corroboration of the opinion that this is a case of olmesartan enteropathy, and this report stands as additional corroboration that olmesartan causes these symptoms. Yasushi Hasebe, the global head of CSPV, based in Japan, was questioned about another adverse event report, and agreed, "that the olmesartan was one of the factors causing the severe diarrhea, dehydration, and hospitalizations described..." (Yasushi Hasebe, 173). These acknowledgements of causality demonstrate CSPV's understanding and acceptance of causality.

Another illustrative example of an adverse event of interest was described by Jeffrey Warmke, the Daiichi Sankyo employee who testified regarding the ROADMAP study. In reviewing an adverse event for a 56 year old female ROADMAP study patient who was in the olmesartan arm of the study, he acknowledged symptoms including diarrhea and vomiting, resulting in hospitalization. The symptoms ceased when the drug was withdrawn, and resumed when the drug was resumed on December 3, 2006 on release from the hospital. The working diagnoses were gastroenteritis and hypokalemia. (Note that per Mr. Warmke, the study investigators were not informed about the adverse event reports indicating severe gastrointestinal symptoms Daiichi Sankyo was seeing, 111-113, 145-146, 157-158). The medication was fully discontinued on December 30, 2006, and the patient was fully recovered by January 31, 2007. Both the investigator and the company assessed the causality as probably related for the

gastroenteritis and hospitalization, with which I concur based on my independent evaluation of the report. Mr. Warmke confirmed that Daiichi Sankyo had first hand knowledge that olmesartan likely caused these symptoms, as this was a study sponsored by Daiichi Sankyo. (Jeffrey Warmke, 327-334).

A recurring issue in a number of the adverse event reports is inclusion of a celiac disease diagnosis in the narrative and/or as a preferred term. This is not surprising, and certainly is not a coincidence, since the symptoms of olmesartan enteropathy are quite similar to celiac disease, and the physicians treating these patients were not likely aware of the risk of olmesartan enteropathy. The recurrent mention of celiac disease in the medical history of adverse event reports points to misdiagnosis of celiac disease during the diagnostic workup of patients who developed olmesartan enteropathy. The literature recognizes the likelihood of physicians misdiagnosing olmesartan enteropathy as celiac disease where the diagnosing physician is not aware of olmesartan enteropathy to be included in the differential diagnosis. Burbure, et al. Olmesartan-associated sprue-like enteropathy: a systematic review with emphasis on histopathology. *Human Pathology* (2016) 50, 127-134.; Marthey L, Cadiot G, Seksik P and Pouderoux P. *Olmesartan-associated enteropathy: results of a national survey*. Aliment Pharmacol Ther. 2014 Nov;40(9):1103-9. . Indeed, in the initial case series describing olmesartan enteropathy, all patients had been treated initially with a gluten-free diet under the initial impression that the diagnosis was celiac disease. Rubio-Tapia A, Herman ML, Ludvigsson JF, Kelly DG, Mangan TF, Wu TT and Murray, JA. Severe Spruelike Enteropathy Associated With Olmesartan. *Mayo Clin Proc*. 2012 Aug;87(8):732-8. In each of these cases, the onset of the symptoms occurred only after the patient began to use olmesartan, providing a temporal



likelihood, especially since it would be unlikely and coincidental for a patient to suddenly develop celiac disease as an adult while using of olmesartan, and it would be virtually impossible for a patient to spontaneously regain tolerance to gluten if the diagnosis were celiac disease, as in each of these cases the patients had successful dechallenges. Application of a differential diagnosis to the information found in these reports establishes that the likely cause of these patients' symptoms was olmesartan in all, or nearly all of these cases.

The likelihood of misdiagnosis of olmesartan enteropathy as celiac disease can be illustrated with specific adverse event reports. For example, a MedWatch for an adverse event reported to Daiichi Sankyo on July 14, 2005, documents a 36 year old male who developed severe vomiting, diarrhea, and weight loss about one year after starting Benicar HCT. The patient was reported to have two positive dechallenges and a positive rechallenge. The patient was "recently" diagnosed with celiac disease. (SU-2005-003790; OLM-DSI-0001099841). Based upon the information documented in the MedWatch this is likely a case of olmesartan enteropathy, based upon the delayed onset of symptoms, the nature of the symptoms, and the positive dechallenges and rechallenge. The recent diagnosis of celiac disease is confounded by the clinical history, particularly the dechallenges and rechallenge, which would not occur in the setting of celiac disease. It is also noteworthy that this report was not included in the analysis of celiac cases prepared by Herve Caspard of CSPV, and Mr. Caspard did acknowledge in his deposition that it should have been included. (Caspard, 290-298). Another example is a MedWatch documenting an adverse event reported to Daiichi Sankyo on September 15, 2005, with regard to a 58 year old female patient who took Benicar for two years then experienced nausea, vomiting, dehydration, and was hospitalized two times. The report and source files

document positive dechallenge and rechallenge. The patient was diagnosed with celiac disease on the day the patient finally stopped taking the drug, after all the symptoms had manifested and after a positive dechallenge and positive rechallenge. (Note: the report indicates that after ceasing the drug on August 31, 2005 the dehydration had resolved, but the status of the low BP, nausea, and vomiting was unknown as of the date of the report, September 15, 2015) Based on the information in the report, this too is likely olmesartan enteropathy, based upon the delayed onset, nature of the symptoms, and the dechallenges and rechallenge. Tina Ho admitted this report should have been included in the celiac report, but was not. (Tina Ho, 427). Herve Caspard authored emails at the time the report was prepared notifying Allen Feldman that this report should have been included in the celiac report, yet it still was not included. (Allen Feldman, 329-330, Exhibit 355). In terms of causality, these reports further support and corroborate the causality for olmesartan enteropathy.

#### **IV. Internal Documents Addressing Olmesartan Enteropathy**

Daiichi Sankyo's internal documents provide foundational information that is helpful in understanding the nature of Olmesartan enteropathy, and the causality. Physicians rely upon information provided by a manufacturer regarding a medication's risks, thus documents and testimony demonstrating what was known but not disclosed is significant since that information, if provided to physicians and patients would be considered and relied on in making treatment decisions. In this context, there are numerous internal documents, and deposition testimony, in which Daiichi Sankyo's employees recognize the causality for olmesartan enteropathy.



Dr. Allen Feldman was the Vice President, Clinical Safety and Pharmacovigilance (“CSPV”), for Daiichi Sankyo in the United States, from June, 2004 to February, 2016. (Allen Feldman, 30-35). One of the key functions of CSPV is to evaluate reports of adverse events to determine if there is a “signal,” meaning information that is unexpected and warrants further review. (Allen Feldman, 68:5-18). A signal can be a syndrome or a combination or constellation of symptoms being reported. (Allen Feldman, 126-127). In looking for signals, a foundational source of information is spontaneous case reports, looking in particular at the temporal sequence, and positive dechallenges and rechallenges. (Allen Feldman, 130-131, 135-137). In this context, Dr. Feldman testified that olmesartan was not intended to have any impacts on the gastrointestinal system, and olmesartan was not expected to cause dehydration, weight loss, villous atrophy, lymphocytic colitis, or microscopic colitis, sprue-like enteropathy or a constellation of symptoms that would look like celiac disease. (Allen Feldman, 69:21-70:10, 76-77, 495-497). Dr. Feldman was asked about a series of adverse event reports demonstrating the clinical syndrome consistent with olmesartan enteropathy, (Allen Feldman, 158-169, 169-172, 185-187, 200-204, 204-206, 228-229, 237-238, 250-254, 260-272, 273-274), and acknowledged that the signal was not seen as these reports came into the company in 2005-2007, and that these cases present a strong signal for this collection of symptoms associated with olmesartan. (Allen Feldman, 257-260, 276-282).

Dr. Feldman testified that the clinical syndrome presented in a March 22, 2007 adverse event report was most likely caused by olmesartan, based on the information set forth, and the only plausible cause was olmesartan. (Allen Feldman, 283-285). Of particular significance, Dr. Feldman also agreed that there was an association, and the only likely cause he could advance

for the clinical syndrome presented by the 22 patients in the Rubio-Tapia Mayo Clinic study was olmesartan, based on the clinical picture including that the symptoms started after the patients started taking the drug, the patients had negative celiac serologies and did not respond to a gluten-free diet, and the patients had positive dechallenges. (Allen Feldman, 181-185). These admissions of causation, with which I agree based upon my independent analysis, by the head of the department responsible to analyze this issue, is strong corroboration and fully consistent with the literature in this area. It is important to note that where Dr. Feldman and other Daiichi Sankyo employees have denied that there is proof that olmesartan causes this syndrome, they have done so with no support, and certainly no support in the peer-reviewed medical literature.

Dr. Feldman was also questioned about a series of reports prepared by Daiichi Sankyo, for internal use, and in some instances to be shared with the FDA, analyzing the adverse event reports the company was receiving. Most important, none of these reports disproves the causality for olmesartan enteropathy. The reports include a November 8, 2010 report prepared to assess 279 adverse event reports of diarrhea received by Daiichi Sankyo between 2002 and 2010. This significant number of reports of diarrhea with olmesartan is consistent with the side effect of severe diarrhea known to occur with the drug, though the report did not assess for clinical details, severity, or causality. Another is the November 12, 2009 report by Dr. Ronke Dosunmu, titled "Olmesartan, olmesartan HCT, and celiac disease." Dr. Donsunmu was concerned about the information she analyzed and recommended further investigation to determine whether a risk needed to be added to the warning. (Allen Feldman, 301-314). This and the January 13, 2010 report authored by Herve Caspard, on the potential association between olmesartan and celiac disease for the FDA are significant for the fact that the company was receiving a large number of

reports indicating a celiac disease diagnosis since misdiagnosis of olmesartan enteropathy as celiac disease is known to occur, especially where the clinician is not aware of the connection between olmesartan and the clinical presentation. The confirmed fact that olmesartan does not contain gluten only strengthens the significance of these reports. (Allen Feldman, 311). Herve Caspard, the CSPV employee who authored the celiac report for the FDA, which correctly concluded that olmesartan does not cause celiac disease, but failed to include all celiac disease cases known to Daiichi Sankyo (See discussion of celiac disease adverse event reports above), and failed to address the causality for **celiac-like** symptoms, also performed a proportional reporting ratio (“PRR”) analysis of the FDA database for celiac disease reports. Dr. Caspard calculated a 23.36 PRR, which was admitted to be a “very high” number, indicating a signal for celiac disease, per Allen Feldman, and per Herve Caspard indicating a statistically significant association. (Allen Feldman, 345, 351; Herve Caspard, 90-94, 104-108, 124, 127). Another of the reports was the September 28, 2012 report on Sprue-like enteropathy, authored by Crawford Parker of CSPV. The report recognizes the significance of the reports of positive rechallenges, and does not in any way disprove causality. In this context, it is interesting to note that Dr. Joseph Murray of the Mayo Clinic, and the senior author of the Rubio-Tapia and Martietta articles, contacted Daiichi Sankyo in 2009, 2010, and 2011 to discuss and obtain information as he was treating a growing number of patients with refractory celiac diagnoses who were using olmesartan. (Allen Feldman, 369-389). Ultimately, Tina Ho confirmed that the people coding the adverse event reports were told that a report of villous atrophy should be deemed sprue-like enteropathy and the syndrome is referred to in the internal memorandum as olmesartan induced enteropathy. (Tina Ho, 460-467; OLM-DSC-0000221307-08). In this context, I have also



reviewed the June 2013 FDA Mini-Sentinel analysis, which showed a higher rate of celiac disease associated with olmesartan use, than for the other ARB's, with a minimum of 2 years exposure.

Hideki Tagawa is a manager in CSPV. (Hideki Tagawa, 11:5-10). Mr. Tagawa discussed an internal powerpoint describing the characteristic symptoms and findings, as well as diagnosis and treatment, for sprue-like enteropathy. The symptoms and findings listed include: severe diarrhea with weight loss, biopsies sometimes reveal intestinal villous atrophy, and inflammation of the lining of the small intestine, and histopathological improvement and improved clinical symptoms when the drug is discontinued. The symptoms listed also include fatty stools, chronic diarrhea, swelling, abdominal bloating, inflammation of skin, tendency to bleed easily, and anemia. The physical exam findings listed include palpebral conjunctiva, oral mucosa, pale skin, pleural fluid, abdominal dropsy, and emaciation (defined as loss of greater than 20% of standard body weight). Finally, the powerpoint indicates that the drug should be discontinued if it is causing the symptoms, an acknowledgment of causation. (Hideki Tagawa, 73-77). Within the same powerpoint is discussion of a fatal sprue-like enteropathy case, where a 70 year old patient had severe diarrhea, dehydration, and a 30 kg weight loss. The conclusion by Daiichi Sankyo is that "causality cannot be denied based on available information," and confirms the drug was the cause of death. (Hideki Tagawa, 57-60). Mr. Tagawa also confirmed that another Japanese language document indicated that the Japanese label was modified to include information about sprue-like enteropathy, because "for the symptoms of severe diarrhea, a causal relationship with drugs containing olmesartan could not be denied." (Hideki Tagawa, 69-70).

Another document containing a very clear statement of causality is the March 7, 2014 “Risk Management Plan for Olmesartan medoxomil/Hydrochlororthiazide.” (Discussed in Tina Ho deposition, November 15, 2016, pages 548-564, Exhibit 731). Tina Ho confirmed that this document was required to be submitted to European regulatory authorities and the information would have to be accurate. (Tina Ho, 550:13-19). First, the Summary of Safety Concerns at table 6, page 63, lists one of the identified risks of olmesartan as “sprue-like enteropathy.” The other identified risks listed in the table include hyperkalemia, and hypotension. This is consistent with the overwhelming scientific consensus. The “risk minimization measures” for olmesartan states: “increase awareness of the risk of sprue-like enteropathy and provide guidance on how to manage that risk,” which Tina Ho confirmed Daiichi Sankyo also tried to do in the United States, by updating the label. (Tina Ho, 556:25-558:10). The document quotes language to be used in the European label for olmesartan, indicating that the “undesirable effects” section will add: “sprue-like enteropathy will be added as a very rare adverse reaction for the monosubstance olmesartan,” which means: “some people, however you would define very rare, they developed sprue-like enteropathy from taking olmesartan.” (Tina Ho, 558:19-559:14). Finally, on page 82 of the document is a table, first identifying the risk of sprue-like enteropathy, and then stating in the “What is known,” column: **“treatment with olmesartan/HCT can lead to severe and chronic diarrhea with substantial weight loss.”** This is a very clear statement recognizing the causality. The third column, “Preventability,” which Tina Ho agreed means: “how do you prevent this side effect from occurring when your – from taking the drug, right, how do you prevent it, right?” The box states the condition is preventable, “by identification of patients at risk and by considering discontinuation of

olmesartan/HCT,” and Tina Ho confirmed this information was, “based on the best knowledge that we have.” (Tina Ho, 559:15-562:21). Again, recognition that the condition is preventable by discontinuing the drug is a strong statement of causation, and fully consistent with the prevailing medical understanding of the condition.

## V. CONCLUSION

In conclusion, there is substantial evidence that, taken on aggregate, establishes the causal relationship between olmesartan and sprue-like enteropathy, to a reasonable degree of medical certainty. The literature began with case series that were followed by numerous case reports worldwide, showing marked improvement of enteropathy upon withdrawal of the drug. This was followed by a population-based cohort study that established a cumulative risk gradient and specificity to olmesartan. The finding of a biologically plausible mechanism provided additional evidence for causality. The significant series of adverse event reports demonstrating patients suffering with the clinical syndrome that characterizes olmesartan enteropathy, and documenting a large number of cases with positive dechallenges and rechallenges, is further important evidence establishing and corroborating the causal relationship. In a commentary on the above-cited French cohort study (Basson M, Mezzarobba M, Weill A, Ricordeau P, Allemand H, Alla F and Carbonnel F. Severe intestinal malabsorption associated with olmesartan: a French nationwide observational cohort study. *Gut*. 2016 Oct;65(10):1664-9.), recently published in the prestigious *Annals of Internal Medicine*, Talley NJ. Use of olmesartan for  $\geq 1$  year was associated with hospitalization for intestinal malabsorption. *Ann Intern Med*. 2015 Dec 15;163(12): Dr. Nicholas Talley writes:



The well-conducted database study by Basson and colleagues puts to bed any controversy surrounding the association between the ARB olmesartan and severe intestinal enteropathy pathologically resembling celiac disease... Evidence supporting a causal relation now includes the strength of association, consistent findings, evidence of improvement in most patients after discontinuation, and relapse on drug reintroduction.

I agree with this conclusion that causality has been established. The listing of olmesartan as a cause of villous atrophy and sprue-like enteropathy is a non-controversial assertion in the medical literature, and confirms the scientific consensus that causality has been established.

Very truly yours,

A handwritten signature in black ink, appearing to read 'B. Lebwohl', written over a horizontal line.

Benjamin Lebwohl, M.D.

November 30, 2016

**Date of preparation:** November 27, 2016

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**Citizenship:** USA

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**ACADEMIC APPOINTMENTS, HOSPITAL APPOINTMENTS, AND OTHER WORK EXPERIENCE**

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**Academic Appointments**

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07/2013 - present	<b>Columbia University College of Physicians &amp; Surgeons</b> Assistant Professor of Medicine and Epidemiology	New York, NY
09/2011 – 06/2013	<b>Columbia University College of Physicians &amp; Surgeons</b> Assistant Professor of Clinical Medicine and Epidemiology	New York, NY
07/2011 – 08/2011	<b>Columbia University College of Physicians &amp; Surgeons</b> Assistant Professor of Clinical Medicine	New York, NY
07/2010 – 06/2011	<b>Columbia University College of Physicians &amp; Surgeons</b> Instructor in Clinical Medicine	New York, NY

**Hospital Appointments**

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07/2010 - present	<b>New York-Presbyterian/Columbia University Medical Center</b> Assistant Attending	New York, NY
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**EDUCATION**

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07/2008 – 06/2010	<b>Columbia University, Mailman School of Public Health</b> MS in Biostatistics, June 2010	New York, NY
08/1999 – 05/2003	<b>Columbia University, College of Physicians &amp; Surgeons</b> MD, May 1999	New York, NY
09/1995 – 06/1999	<b>Harvard College</b> AB in Music, June 1999	Cambridge, MA

**TRAINING**

07/2007 – 6/2010	<b>Division of Digestive and Liver Diseases, Department of Medicine, NewYork Presbyterian Hospital/Columbia</b> Gastroenterology Fellow	New York, NY
06/2006 – 05/2007	<b>Department of Medicine, NewYork Presbyterian Hospital/Columbia</b> Chief Medical Resident	New York, NY
06/2003 – 06/2006	<b>Department of Medicine, NewYork Presbyterian Hospital/Columbia</b> Medicine Resident	New York, NY

**LICENSURE AND BOARD CERTIFICATION**

New York State license #233671  
 ABIM certified for internal medicine 2006 through 2016  
 ABIM certified for gastroenterology 2010 through 2020

**HONORS AND AWARDS*****Awards***

2015-2018: Ewig Clinical Scholar Award, in recognition of clinical teaching.

2014-2017: Lewis V. Gerstner, Jr. Scholar, Columbia University. Awarded to four young physician-scientists at the College of Physicians and Surgeons at Columbia University to conduct translational research.

2013-2016: Irving Scholar Award. Approximately 4 awardees annually, open to applicants from all clinical departments at the College of Physicians and Surgeons at Columbia University Medical Center.

2013: American Gastroenterology Association/Gastroenterology Research Group Young Investigator Award in Clinical Science. (One annual awardee)

2010: Recipient, Clinical Reviewer Award, Gastrointestinal Endoscopy.

2008: Physician of the Year Award, fellow category, presented by the Department of Nursing at NewYork Presbyterian Hospital.

2004: Inductee, Arnold P. Gold Foundation Circle of Excellence, elected by third-year medical students.

2004: Winner for intern class, Department of Medicine House Staff Award, in recognition of excellence in clinical



teaching at NewYork Presbyterian Hospital. (One annual awardee)

2003: Inductee, Alpha Omega Alpha.

1999: Joseph Garrison Parker Prize, awarded to a student who intends the profession of medicine and who has an unusual breadth of interests outside the specifically premedical curriculum. (One annual awardee)

1999: Inductee, Phi Beta Kappa.

***Invited Lectureships***

2016: Gastroenterology Grand Rounds, Weill Cornell Medical Center: "What's Going On with Gluten?"

2016: Gastroenterology Grand Rounds, SUNY Downstate Medical Center: "Update on Celiac Disease and Gluten Sensitivity"

2016: Pediatric Gastroenterology Grand Rounds, Columbia University: "Update on Celiac Disease and Gluten Sensitivity"

2016: American Gastroenterological Association Regional Practice Skills Workshop, New York. "Academic Practice"

2016: Gastroenterology Grand Rounds, Lennox Hill Hospital, New York: "What's Going On with Gluten?"

2015: American Society of Nutrition, Advances and Controversies in Clinical Nutrition, Long Beach, CA. "Gluten Sensitivity: New Epidemic or Current Craze?"

2015: Lecturer and Dissertation Opponent: University of Umeå, Sweden. "The Multifactorial Etiology of Celiac Disease"

2015: Division of General Medicine Grand Rounds, Columbia University. "Update on Colorectal Cancer Screening and Colonoscopy Quality."

2015: Session Chair and Speaker, International Celiac Disease Symposium, Prague, Czech Republic. "Mechanisms and possible modulation of refractory celiac disease"

2015: Digestive Disease Week, Washington, DC. "Suspected Celiac Disease: How to Secure a Diagnosis?"

2015: Department of Medicine Grand Rounds, Columbia University; John Loeb Lecture. "Celiac Disease: Causes and Consequences"

2015: Peter D. Stevens Course on Innovations in Digestive Care, New York. "Diagnosis and Treatment of Celiac Disease"

2015: Food and Drug Administration Conference: Gastroenterology Regulatory Endpoints and the Advancement of Therapeutics, Washington, DC. "Role of Histology to Measure Clinical Benefit and Appropriate Timing of Assessment"

2014: New York Society for Gastrointestinal Endoscopy Annual Course, New York. "Update on Diagnosis and Managing Celiac Disease."

2014: Digestive Disease Week, Chicago, IL. "Screening and Diagnosing Celiac Disease: What Are the Benefits?"

2014: Gastroenterology Grand Rounds, Lennox Hill Hospital, New York: "Update on Celiac Disease and Gluten Sensitivity"

2014: Pediatric Gastroenterology Grand Rounds, Weill Cornell Medical Center, New York: "Update on Celiac Disease and Gluten Sensitivity"

2013: Gastroenterology Grand Rounds, Weill Cornell Medical Center, New York: "Studying Celiac Disease with Large Data Sets"

2013: Gastroenterology Grand Rounds, NYU Langone Medical Center: "Studying Celiac Disease with Large Data Sets"

2013: International Celiac Disease Symposium, Chicago, IL. "Correct Diagnostic Approach"

2013: International Celiac Disease Symposium, Chicago, IL. "What Happens When Your Diet is Less Than Scrupulous"

2013: Research Forum Co-chair, Digestive Disease Week, Orlando, FL. "Advances in Celiac Disease Diagnosis"

2013: Medical Epidemiology and Biostatistics, Karolinska Institute, Stockholm Sweden: "Decreased Risk of Celiac Disease in Patients with Helicobacter pylori Colonization"

2012: Research Forum Co-chair, Digestive Disease Week, San Diego, CA. "Celiac Disease: Neither Rare Nor Trivial"

2012: Gastroenterology Grand Rounds, Mount Sinai Hospital, New York: "Studying Celiac Disease with Large Data Sets"

2012, 2015: Keynote Address, Columbia University Department of Medicine Intern Retreat

2012: Career Forum Panelist: Careers in Epidemiology. Mailman School of Public Health, Columbia University.

2011: Clinical Epidemiology Unit, Karolinska Institute, Stockholm Sweden. "Adherence to Biopsy Guidelines Increases Celiac Disease Diagnosis"

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#### ACADEMIC SERVICE

2015-present: Gastroenterology Fellowship Clinical Competence Committee

2015-present: Gastroenterology Fellowship Evaluation Committee



- These two committees meet quarterly for the purpose of monitoring the performance of each gastroenterology fellow and to develop structural changes to the fellowship program in response to fellow feedback.

2014-present: Society of Practitioners Executive Council

- The Society of Practitioners is an association of practicing faculty, both full-time and voluntary, at Columbia University who are dedicated to the betterment of both patient care and professional activities at our medical center. This group is independent of both the University and the Hospital. The Executive Council meets monthly with the hospital leadership to discuss issues related to patient care of mutual concern to physicians and administration.

2014-2015: Epidemiology General Exam Committee

- We developed and graded the general (written) exam for PhD candidates in Epidemiology at the Mailman School of Public Health.

2013-present: Digestive Disease Week Abstract Review Committee

- I serve on a four-person committee of the American Gastroenterological Association that evaluates all abstracts related to celiac disease submitted to this annual national meeting.

2013-present: Tripartite Request Assessment Committee (TRAC)

- This committee, consisting of representatives from Columbia University Medical Center, Weill Cornell Medical Center, and NewYork Presbyterian Hospital, evaluates all requests for clinical data for the purposes of quality improvement or research projects. The committee meets weekly by teleconference.

2011-present: ColumbiaDoctors Quality Committee

- This committee meets monthly to develop policies and procedures for the faculty practice of Columbia University Medical Center, with an emphasis on implementation of the electronic medical record and monitoring adherence to federally mandated reporting measures.

2011-present: Academic Advisor, Mailman School of Public Health

- I would meet twice yearly (and more often as needed) with masters degree candidates, providing advice on course selection, courseload, and career plans for the following students:
  - Wai Sha (Sally) Cheung, '14
  - Ravi Pasam, '14
  - Katherine Infante, '15
  - Mirko Savone, '16
  - Richa Gupta, '16
  - Aster Meche, '17
  - Matthew Cato, '17
  - Francesco DeMayo, '17

2011-present: Thesis Reader in Epidemiology

- I read drafts and graded the final masters thesis for the following students at the Mailman School of Public Health:
  - Tim Wen: 2011-2012
  - Stephen Mooney: 2011-2012
  - Miriam Gofine: 2014-2015



- Kirsten Quiles: 2014-2015
- Kevin Yao: 2015-2016
- Trang Tran: 2015-2016

2010-present Medicine House Staff Recruiting Committee

2010-present: Gastroenterology Fellowship Recruiting Committee

- My participation in the above two committees consists of interviewing candidates for these programs and attendance of ranking sessions.

## **PROFESSIONAL ORGANIZATIONS AND SOCIETIES**

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### **MEMBERSHIPS AND POSITIONS**

2016-present: member, Research Policy Committee, American Gastroenterological Association

2015-present: member, Research Advocacy Subcommittee, Government Affairs Committee, American Gastroenterological Association

2013-2015: Treasurer, North American Society for the Study of Celiac Disease

2011-present: member, North American Society for the Study of Celiac Disease

2011-2015: member, Intestinal Disorders Committee, American Gastroenterological Association

2010-present: member, Herbert Irving Comprehensive Cancer Institute

2008-present: member, American Society for Gastrointestinal Endoscopy

2009-present: member, American College of Gastroenterology

2006-present: member, American Gastroenterological Association

### **CONSULTATIVE**

2015-2016: New York City Department of Health and Mental Hygiene, Colon Cancer Continuous Quality Improvement Toolkit

2015-present: American Association of Medical Colleges: Public Health in Medical Education Task Force

2014-present: Medical Advisory Board, Executive Health Examinations

2014-present: Scientific Advisory Board, National Foundation for Celiac Awareness

### **JOURNAL REVIEWER**

New England Journal of Medicine

JAMA

Gastroenterology  
Gut  
Clinical Gastroenterology and Hepatology  
Digestive Diseases and Sciences  
Gastrointestinal Endoscopy  
Alimentary Pharmacology and Therapeutics  
Journal of Clinical Gastroenterology  
Clinical Biochemistry  
American Journal of Gastroenterology

#### EDITORIAL BOARDS

2016-present: Clinical and Translational Gastroenterology  
2013-present: Digestive Diseases and Sciences

#### FELLOWSHIP AND GRANT SUPPORT

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- **PRESENT SUPPORT**

AGA Research Scholar Award 7/1/2014-6/30/2017  
\$270,000

**Risk Factors for Celiac Disease and the Health Effects of Gluten**

This set of studies involves analyses of the Harvard cohorts so as to determine environmental risk factors for celiac disease, and the development of a gluten index with the aim of determining whether gluten exposure is associated with cardiovascular outcomes.

Louis V. Gerstner, Jr. Scholar 7/1/2014-6/30/2017  
\$225,000

**Gluten and the Microbiome in Individuals With Celiac Disease and Non-Celiac Gluten Sensitivity**

This study investigates the microbiome as it relates to the symptomatic effects of gluten. We will conduct a 14-day gluten challenge in patients with celiac disease and in a separate group with non-celiac gluten sensitivity and measure gut microbial composition during this exposure. We will determine whether the severity of gastrointestinal and extraintestinal symptoms experienced during gluten exposure is correlated with reduced species diversity.

- **PAST SUPPORT**

Irving Scholar Award 7/1/2013-6/30/2016  
UL1 TR000040  
\$180,000

**The "Celiac Stomach": Gastric Environment and the Risk of Celiac Disease**

This set of studies aims to determine whether the risk of celiac disease is affected by exposures to the gastric mucosa, including *Helicobacter pylori* colonization and acid suppression medication.

Alvine Pharma (site PI)  
\$228,894

8/1/2013-12/1/2014

**Evaluation of the Efficacy and Safety of ALV003 in Symptomatic in Celiac Disease Patients**

Phase IIB randomized trial of an endopeptidase/endoprotease agent for patients with celiac disease and persistent symptoms with histologic abnormalities.

Alvine Pharma (site PI)  
\$51,876

1/1/2013-12/31/2013

**Evaluation of Patient Reported Outcome Instruments in Celiac Disease Patients**

Validation study measuring the sensitivity of patient reported outcome instruments to detect change over time in celiac disease symptoms with and without a gluten challenge.

National Center for Advancing Translational Sciences/National Institutes of Health 7/1/2011-6/30/2013  
KL2 RR024157  
\$200,000

**Quality Issues in the Diagnosis of Celiac Disease**

Mentors: Alfred I. Neugut and Peter Green

This study aims to identify the underlying causes of the low rates of diagnosis of celiac disease in the United States. The goal of this mentored career development award is to facilitate junior faculty members to achieve research independence.

National Cancer Institute training grant (PI: Alfred I. Neugut)  
T32-CA095929

7/1/2008-6/30/2010

Mentor: Alfred I. Neugut

**Colorectal Cancer Prevention**

As a fellow on this training grant I studied risk factors for suboptimal bowel preparation on colonoscopy using observational data sets.

Celiac Sprue Association (Benjamin Lebwohl)  
\$5,000

7/1/2011-6/30/2012

**Serial Biopsies and Mortality in Celiac Disease: a Population-Based Study**

The grant supplements the travel expenses associated with my ongoing collaboration with the Clinical Epidemiology Unit at the Karolinska Institute in Stockholm, Sweden

American Scandinavian Foundation (Benjamin Lebwohl):  
\$5,000

5/1/2011-8/31/2011

**Serial Biopsies and Mortality in Celiac Disease: a Population-Based Study**

The objective of this study is to determine whether the results of the "control biopsy," performed 1-3 years following the initial diagnosis of celiac disease, is associated with the mortality rate, which is overall increased in celiac disease. This study utilizes a population-based database of all patients in Sweden with celiac disease spanning the years 1969-2008.

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**EDUCATIONAL CONTRIBUTIONS**

*Direct Teaching/Precepting/Supervising*



2010-present: General Medicine Inpatient Service

- For a 4-week period every year I serve as attending physician on this service (consisting of 2 interns, 2 residents, and 2 attendings including myself) which cares for inpatients with a variety of general medical illnesses. Rounds, which combine teaching and direct patient care, are performed daily for 2-3 hours.

2010-present: Gastroenterology consultation service

- For 1-2 2-week periods every year I serve as the attending physician on this service (consisting of 2-3 GI fellows and 1-2 medical students or residents) which cares for inpatients in need of gastroenterology consultation. Until 2015 this service included the supervision of endoscopic procedures on consulted patients.

2010-present: Gastroenterology clinic

- For 3-5 4-hour sessions every year I serve as the attending in this outpatient clinic in which GI fellows care for patients with a variety of gastrointestinal illnesses.

2011-present: Lecturer and Small Group Leader, The Body in Health and Disease (M6107)

- I give a 1 hour lecture annually to second-year medical students on the topic of diarrhea covering epidemiology, pathophysiology, differential diagnosis, and treatment. I also precept the students in 2-4 sessions during a 2 week period annually, reviewing case-based questions.

2015: Epidemiology 1

- I was a guest lecturer on the topic of screening for this introductory course for masters students in public health.

2012-present: Section teacher, Clinical Reasoning and Decision Analysis course

- Twice a year I lead medical students in 2 90-minute sessions consisting of case-based discussions in the areas of cognitive bias and decision analysis.

***Development of instructional material and curriculum used locally***

2015-present: Public Health Thread

- I was appointed the director of this curricular initiative with the objective of incorporating public health into the four years of the medical school curriculum. This includes preclinical lectures on the topics of public health in clinical practice, the development of case-based clinical discussions on topics relating to public health that are relevant to medical students and residents, and the development of a public-health-oriented patient write-up assignment during the medicine rotation in the Major Clinical Year. I delivered a one-hour lecture titled, "What is Public Health?" in March 2016 to the medical students as part of the Mechanisms and Practice component of their Major Clinical Year.

2012-present: Co-Director, Postgraduate Course: Update in Gastroenterology, Hepatology, & Nutrition

- I develop the program for this annual 2-day course that is jointly taught by faculty of Columbia University Medical Center and Weill Cornell Medical Center. Targeted toward a nationwide audience of gastroenterologists, internists, medical oncologists, nutritionists and surgeons, the course focuses on important recent developments and current controversies in gastrointestinal and liver disease. Attendance ranges from 100-200 participants annually.

***List of Mentees***

2015-present: Jude Fleming: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: the impact of the gluten-free diet on lamina propria eosinophil concentration among patients with newly-diagnosed celiac disease.

2015-present: Anna Krigel: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: ethnic variation in celiac disease prevalence in the United States.

2015-present: Monika Laszkowska: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: the impact of case start time delays on adenoma detection rates among patients undergoing screening colonoscopy.

2015-present: Rajani Sharma: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: adherence to national guidelines for proton pump inhibitor prescription in patients receiving combination aspirin and anticoagulation.

2015-present: Lauren Golden: Fourth-year medical student at Columbia College of Physicians and Surgeons. Scholarly Project: predictors of persistent villous atrophy among patients with celiac disease undergoing follow-up biopsy.

2015-present: Shria Kumar: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: incidence and predictors of gastrointestinal bleeding among patients admitted to a medical intensive care unit.

2014-present: Abhik Roy: Fellow in gastroenterology at NewYork Presbyterian Hospital/Columbia. Project: evaluation of adherence to surveillance intervals after navigator-facilitated colonoscopy.

2013-2014: Janie Yang: Fourth-year medical student at Columbia College of Physicians and Surgeons. Scholarly project: Cost Effectiveness of Routine Duodenal Biopsy during Endoscopy to Evaluate Esophageal Reflux. Currently a resident in internal medicine at Mount Sinai Hospital.

2013-present: SriHari Mahadev: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia (and currently a fellow in GI at the same institution). Projects: bowel preparation quality and its impact on adenoma detection, dietician use and celiac disease; predictors of persistent villous atrophy in celiac disease.

2013-2015: Ruby Greywoode: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: the association of olmesartan use with the presence of diarrhea among patients undergoing endoscopic procedures. Currently a GI fellow at Mount Sinai Hospital.

2013-2014: Eric Braunstein: Fourth-year medical student at Columbia College of Physicians and Surgeons. Project: Development of a clinical prediction rule for difficult sedation in patients undergoing endoscopic



procedures. Currently a resident in internal medicine at Mount Sinai Hospital.

2011-2014: Anna Tavakkoli: Resident in internal medicine at NewYork Presbyterian Hospital/Columbia. Project: vitamin D levels and autoimmunity in patients with celiac disease; long-term outcomes in individuals with non-celiac gluten sensitivity. Currently a GI fellow at the University of Michigan.

2011-2015: Max Pitman: Fourth-year medical student at Columbia College of Physicians and Surgeons. Project: predictors of duodenal biopsy among patients undergoing upper gastrointestinal endoscopy. Currently a first-year GI fellow at New York University Langone Medical Center.

2010-2012: David Narotsky: Medical student at Johns Hopkins University School of Medicine. Project: bibliometric analysis of celiac disease publications. Currently a Resident in Internal medicine at NewYork Presbyterian Hospital/Columbia.

### ***Educational Administration and Leadership***

2015-present: Gastroenterology Fellows Quality Improvement Projects

- In partnership with the fellowship program leadership, I developed a team-based quality improvement program in which teams of 3-4 fellows, under the guidance of a faculty member, collaborate on an annual project related to improving clinical practice, with an emphasis on identification of systems inefficiencies and measurement of outcomes. Teams present their findings at an annual faculty meeting dedicated Quality Improvement. Teams have the option to obtain Institutional Board Review approval so as to publish their findings.

### ***Instructional/Educational Materials used in Print or other Media***

2015: "Don't Just Go Gluten-Free; Why You Need to be Tested First"

- I provided the content and led this Webinar that was hosted by the National Foundation for Celiac Awareness.

### ***Community Education***

2016: Presentation, Gluten Intolerance Group of Richmond, Virginia

2013: Presentation, Gluten Intolerance Group of Asheville, North Carolina

2014: Presentation, Colin Leslie Walk for Celiac Disease Research

2012, 2015: Presentation, gluten-free family weekend retreat, New Jersey Y Summer Camps.

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## **REPORT OF CLINICAL AND PUBLIC HEALTH ACTIVITIES AND INNOVATIONS**



***Practice or Public Health Activities***

2010-present: Gastroenterology clinical practice

- My clinical practice focuses on celiac disease and other gluten-related disorders, as well as general gastroenterology. I perform office consultation and procedures (upper gastrointestinal endoscopy and colonoscopy) with patient contact totaling 10 hours weekly.

***Clinical or Public Health Innovations***

2011-present: Screening Colonoscopy Report Cards

- In collaboration with information technology personnel at NewYork Presbyterian Hospital, I developed a system for the measurement of colonoscopy quality indicators including the adenoma detection rate, which is widely regarded as the most important process measure in screening colonoscopy. We distributed report cards to gastroenterology faculty, comparing the recipient's adenoma detection rate to his/her peers, using anonymized suite-wide reporting. To my knowledge we were the first academic medical center in New York City to provide benchmarked feedback to providers regarding their adenoma detection rates. Our method of reporting has been incorporated into the Colonoscopy Quality Improvement Toolkit developed by the New York City Department of Health and Mental Hygiene.

***Clinical or Public Health Administration and Leadership***

2016-present: Director of Quality Improvement, Division of Digestive and Liver Disease

2015-2016: Co-Director of Quality Improvement, Division of Digestive and Liver Disease

- I review all cases of potential medical errors related to adverse outcomes in the division of gastroenterology, submitting written reports to the Quality and Patient Safety Committee of NewYork Presbyterian Hospital.

***Additional Clinical or Public Health Service Activities***

2016-present: Co-Chair, Quality Committee, Citywide Colon Cancer Control Coalition (C5) (member since 2010)

- Under the auspices of the New York City Department of Health and Mental Hygiene, this coalition consists of physicians, allied health professionals, and public health officials, with the aim of increasing the rate of screening for colorectal cancer and improving the quality of screening. As a Co-chair of the Quality Committee (which meets in person semiannually and hosts 2-3 additional conference calls per year) I have advised the coalition on the choice of benchmarks and methods of reporting.

**PATENTS & INVENTIONS**

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None

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**PUBLICATIONS**

*Original, Peer-Reviewed Publications*

1. Blackett JW, Rosenberg R, Mahadev S, Green PH, \***Lebwohl B**. Adenoma Detection is Increased in the Setting of Melanosis Coli. J Clin Gastroenterol. 2016; in press.
2. Ludvigsson JF, **Lebwohl B**, Ekblom A, Kiran R, Green PH, Höijer J, Stephansson O. Outcomes of pregnancies for women undergoing endoscopy while they were pregnant-a nationwide cohort study. Gastroenterology. 2016; in press.
3. Kumar S, Gress F, Green PH, \***Lebwohl B**. Chronic pancreatitis is a common finding in celiac patients who undergo endoscopic ultrasound. J Clin Gastroenterol. 2016; in press.
4. Roy A, Mehra S, Kelly CP, Tariq S, Pallav K, Dennis M, Peer A, **Lebwohl B**, Green PH, Leffler DA. The association between socioeconomic status and the symptoms at diagnosis of celiac disease: a retrospective cohort study. Therap Adv Gastroenterol 2016;9:495-502.
5. Laszkowska M, Roy A, **Lebwohl B**, Green PH, Sundelin HE, Ludvigsson JF. Nationwide population-based cohort study of celiac disease and risk of Ehlers-Danlos syndrome and joint hypermobility syndrome. Dig Liver Dis. 2016;48:1030-4.
6. Roy A, Laszkowska M, Sundström J, **Lebwohl B**, Green P, Kämpe O, Ludvigsson JF. Prevalence of celiac disease in patients with autoimmune thyroid disease - a meta-analysis. Thyroid. 2016;26:880-90.
7. Kuja-Halkola R, **Lebwohl B**, Halfvarson J, Wijmenga C, Magnusson PK, Ludvigsson JF. Heritability of non-HLA genetics in coeliac disease: a population-based study in 107,000 twins. Gut 2016; in press.
8. Krigel A, Turner KO, Makharia GK, Green PH, Genta RM, \***Lebwohl B**. Ethnic Variations in Duodenal Villous Atrophy Consistent with Celiac Disease in the United States. Clin Gastroenterol Hepatol. 2016;14:1105-11.
9. Roy A, Minaya M, Monegro M, Fleming J, Wong RK, Lewis S, **Lebwohl B**, Green PH. Partner Burden: A Common Entity in Celiac Disease. Dig Dis Sci 2016;61:3451-3459.
10. **Lebwohl B**, Roy A, Alaedini A, Green PH, Ludvigsson JF. Risk of Headache-Related Healthcare Visits in Patients With Celiac Disease: A Population-Based Observational Study. Headache. 2016; in press.
11. Reilly NR, **Lebwohl B**, Mollazadegan K, Michaëlsson K, Green PH, Ludvigsson JF. Celiac disease does not influence fracture risk in young patients with type 1



- diabetes. *J Pediatr. J Pediatr.* 2016;169:49-54.
12. Mahadev S, Gardner R, Lewis SK, **Lebwohl B**, Green PH. Quality of Life in Screen-detected Celiac Disease Patients in the United States. *J Clin Gastroenterol.* 2016;50:393-7.
13. **Lebwohl B**, Luchsinger JA, Freedberg DE, Green PH, Ludvigsson JF. Risk of dementia in patients with celiac disease: a population-based cohort study. *J Alzheimers Dis.* 2015;49:179-85.
14. Roy A, Pallai M, **Lebwohl B**, Taylor AK, Green PH. Attitudes Toward Genetic Testing for Celiac Disease. *J Genet Couns.* 2016;25:270-8.
15. Emilsson L, **Lebwohl B**, Sundström J, Ludvigsson JF. Cardiovascular disease in patients with coeliac disease: A systematic review and meta-analysis. *Dig Liver Dis.* 2015;47:847-52.
16. Mårild K, **Lebwohl B**, Green PH, Murray JA, Ludvigsson JF. Blockers of angiotensin other than olmesartan in patients with villous atrophy: a nationwide case-control study. *Mayo Clin Proc.* 2015;90:730-7.
17. **Lebwohl B**, Green PH, Genta RM. The coeliac stomach: gastritis in patients with coeliac disease. *Aliment Pharmacol Ther.* 2015;42:180-7.
18. Thawani SP, Brannagan TH 3rd, **Lebwohl B**, Green PH, Ludvigsson JF. Risk of neuropathy among 28 232 patients with biopsy-verified celiac disease. *JAMA Neurol.* 2015;72:806-11.
19. Yang JJ, Thanataveerat A, Green PH, \***Lebwohl B**. Cost effectiveness of routine duodenal biopsy analysis for celiac disease during endoscopy for gastroesophageal reflux. *Clin Gastroenterol Hepatol.* 2015;13:1437-43.
20. Jensen ET, Eluri S, **Lebwohl B**, Genta RM, Dellon ES. Increased risk of esophageal eosinophilia and eosinophilic esophagitis in patients with active celiac disease on biopsy. *Clin Gastroenterol Hepatol.* 2015;13:1426-31.
21. Latorre M, Lagana SM, Freedberg DE, Lewis SK, **Lebwohl B**, Bhagat G, Green PH. Endoscopic biopsy technique in the diagnosis of celiac disease: one bite or two? *Gastrointest Endosc* 2015;81:1228-33.
22. Reilly NR, **Lebwohl B**, Hultcrantz R, Green PH, Ludvigsson JF. Increased risk of nonalcoholic fatty liver disease after diagnosis of celiac disease. *J Hepatol* 2015;62:1405-11.
23. **Lebwohl B**, Emilsson L, Fröbert O, Einstein AJ, Green PH, Ludvigsson JF. Mucosal healing and the risk of ischemic heart disease or atrial fibrillation in patients with celiac disease; a population-based study. *PLoS One* 2015;10:e0117529.
24. **Lebwohl B**, Stephansson O, Green PH, Ludvigsson JF. Mucosal healing in patients with celiac disease and outcomes of pregnancy: a nationwide population-based



study. Clin Gastroenterol Hepatol 2015;13:1111-1117.

25. Abu-Zeid YA, Jasem WS, **Lebwohl B**, Green PH, ElGhazali G. Seroprevalence of celiac disease among United Arab Emirates healthy adult nationals: A gender disparity. World J Gastroenterol. 2014;20:15830-6.
26. Hillyer GC, **Lebwohl B**, Rosenberg RM, Neugut AI, Wolf R, Basch CH, Mata J, Hernandez E, Corley DA, Shea S, Basch CE. Assessing bowel preparation quality using the mean number of adenomas per colonoscopy. Therap Adv Gastroenterol. 2014;7:238-46.
27. Lagana SM, Braunstein ED, Arguelles-Grande C, Bhagat G, Green PH, **\*Lebwohl B**. Sprue-like histology in patients with abdominal pain taking olmesartan compared with other angiotensin receptor blockers. J Clin Pathol. 2015;68:29-32.
28. Nazareth S, **Lebwohl B**, Tennyson CA, Simpson S, Greenlee H, Green PH. Dietary Supplement Use in Patients With Celiac Disease in the United States. J Clin Gastroenterol. 2015;49:577-81.
29. Mahadev S, Green PH, **\*Lebwohl B**. Rates of Suboptimal Preparation for Colonoscopy Differ Markedly Between Providers: Impact on Adenoma Detection Rates. J Clin Gastroenterol. 2015;49:746-50.
30. Greywoode R, Braunstein ED, Arguelles-Grande C, Green PH, **\*Lebwohl B**. Olmesartan, other antihypertensives, and chronic diarrhea among patients undergoing endoscopic procedures: a case-control study Mayo Clin Proc. 2014;89:1239-43.
31. **Lebwohl B**, Sundström A, Jabri B, Kupfer SS, Green PH, Ludvigsson JF. Isotretinoin use and celiac disease: a population-based cross-sectional study. Am J Clin Dermatol 2014;15(6):537-42.
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33. Braunstein ED, Rosenberg R, Gress F, Green PH, **\*Lebwohl B**. Development and validation of a clinical prediction score (the SCOPE score) to predict sedation outcomes in patients undergoing endoscopic procedures. Aliment Pharmacol Ther. 2014;40:72-82.
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improve detection of celiac disease in patients with iron deficiency anemia. *Am J Gastroenterol* 2014;109:769-70.

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40. **Lebwohl B**, Murray JA, Rubio-Tapia A, Green PH, Ludvigsson JF. Predictors of persistent villous atrophy in coeliac disease; a population-based study. *Aliment Pharmacol Ther* 2014;39:488-95.
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control study. *BMC Gastroenterol.* 2013;13:109.

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52. Mahadev S, Simpson S, **Lebwohl B**, Lewis SK, Tennyson CA, Green PH. Is dietitian use associated with celiac disease outcomes? *Nutrients.* 2013;5:1585-94.
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and inflammatory bowel disease. Headache. 2013;53:344-55.

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***Letters to the Editor***

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**INVITED AND/OR PEER-SELECTED PRESENTATIONS AT REGIONAL, NATIONAL OR INTERNATIONAL LEVELS:**

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See *Invited Lectureships* section in **Honors and Awards**